IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF DONALD R. OSTERGARD, M.D.

Plaintiffs do not oppose Ethicon's motion to exclude Dr. Ostergard's testimony regarding the alleged carcinogenicity of the polypropylene in Gynemesh, or his testimony on Ethicon's "state of mind." Pls.' Opp'n (Dkt. 2950) at 5.[1] Accordingly, the Court should grant Ethicon's motion to exclude Dr. Ostergard's testimony on these topics.

Plaintiffs also effectively concede the inadmissibility of Dr. Ostergard's opinions that four meshes he discusses in his report are safer alternatives to Gynemesh PS. Plaintiffs state that Dr. Ostergard will not testify that any of these devices are safer alternatives, but argue nonetheless that the Court should deny Ethicon's challenge because these opinions are merely making a broader point that lower-weight meshes are preferable. Plaintiffs' *post hoc*, unsupported recharacterization cannot salvage Dr. Ostergard's opinions. His opinions are unsupported and should therefore be excluded as unreliable.

[1] "Defendants" and "Ethicon" refer collectively to Ethicon, Inc. and Johnson & Johnson. Ethicon LLC, recently dismissed by the Court, *see* Pretrial Order # 241 (Dkt. 2961) at 1, is not a named defendant in any of the Wave 3 cases in which Plaintiffs have designated Dr. Ostergard as a general-causation expert. *See* Ex. A to Defs.' Mot. (Dkt. 2814-1) (listing cases).

Plaintiffs similarly attempt to recharacterize Dr. Ostergard's infection-related opinions as "not related to infection" because some mention alleged defects that Plaintiffs assert can cause other complications in addition to infection. Plaintiffs' argument fails. Ethicon's challenge is to specific, infection-related opinions. The Court should exclude these opinions as irrelevant in cases in which a mesh-related infection is not alleged.

The Court should also exclude Dr. Ostergard's opinions regarding FDA regulatory requirements and what warnings should be included in the IFU because he does not have the additional expertise required to offer these opinions. While Plaintiffs recite Dr. Ostergard's general qualifications at length, they do not identify any specific expertise that qualifies him to offer his proposed testimony on these topics.

Finally, the Court should exclude Dr. Ostergard's proposed testimony on Ethicon's intentions and narrative review of corporate documents as unhelpful to the jury. Plaintiffs do not address any of the specific testimony challenged by Ethicon, nor do they explain how this testimony survives the Court's repeated rulings that this testimony is inadmissible. It should be excluded.

Ethicon therefore requests that the Court grant its motion to exclude Dr. Ostergard's general-causation testimony, as detailed below and in Ethicon's memorandum.

ARGUMENTS AND AUTHORITIES

I. Dr. Ostergard's safer-alternatives opinions should be excluded as unreliable.

Ethicon's motion seeks to exclude Dr. Ostergard's opinions that Polyform, Popmesh, Pelvitex, and Timesh are safer alternatives to Gynemesh PS. Defs.' Mem. (Dkt. 2816) at 2-5. Plaintiffs concede this argument, stating that Dr. Ostergard "will not testify that ANY of these four devices are a safer alternative device to the Gynemesh PS." Pls.' Opp'n (Dkt. 2950) at 5. The Court should therefore grant Ethicon's motion to exclude testimony on this topic.

Plaintiffs in their opposition, however, attempt to salvage the challenged opinions by recharacterizing them as "simply discussing the notion [that] Gynemesh when compared to other products already on the market was heavier weight and stiffer" because "[l]ower weight and decreased stiffness are two qualities that Dr. Ostergard believes are necessary as part of an alternative design." *Id.* at 6. In support, Plaintiffs recite several paragraphs from a different part of Dr. Ostergard's report, in which he summarizes his interpretation of various studies and articles regarding unidentified meshes that are purportedly less stiff than Gynemesh PS. *Id.* at 6-7. Plaintiffs' characterization of the challenged opinions is inaccurate, and their recitation of statements they contend support their mischaracterization does not advance their argument. Dr. Ostergard stated in his report that Popmesh and Polyform are "preferred" to Gynemesh PS and that the stiffness of Gynemesh PS is a "detrimental quality" in comparison to Polyform, Pelvitex, and Timesh. *See* Ex. B to Defs.' Mot. (Dkt. 2814-2) at 3-4. As Ethicon explained, the opinions regarding these specific meshes are unreliable because the two articles Dr. Ostergard relied on in forming them do not support his opinions, Dr. Ostergard admitted that he was aware of no other studies that would support these opinions, and Dr. Ostergard ultimately conceded that he would not testify that these four meshes are suitable alternatives to Gynemesh PS. Defs.' Mem. (Dkt. 2816) at 4-5. The challenged opinions should therefore be excluded as unreliable.

II. Dr. Ostergard's infection opinions should be excluded as irrelevant.

Ethicon also asks the Court to exclude Dr. Ostergard's infection-related opinions in cases where infection is not at issue. Defs.' Mem. (Dkt. 2816) at 7-8; *see also, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536456, at *3 (S.D.W. Va. Aug. 30, 2016) (excluding Dr. Ostergard's general-causation opinions as to complications not

alleged or experienced by any of the applicable plaintiffs).[2] Ethicon identified the specific infection-related opinions that would be irrelevant in non-infection cases; each of these opinions asserts that infection is more likely because of particular characteristics of Gynemesh PS. Defs.' Mem. (Dkt. 2816) at 7-8. Plaintiffs nonetheless assert that "these opinions are not opinions on infection" because they "focus[] on specific defects within the design of the mesh that create all manner of complications including erosion, pain, and inflammation: with or without infection." Pls.' Opp'n (Dkt. 2950) at 8. Plaintiffs are wrong. Dr. Ostergard's opinion that, for instance, the pore size of Gynemesh PS "allow[s] bacteria to enter and to hide from the host defenses designed to eliminate them" (*see* Ex. B to Defs.' Mot. (Dkt. 2814-2) at 2-3) is an infection-related opinion that is not relevant—and should therefore be excluded—in a non-infection case. To the extent that Dr. Ostergard holds opinions that pore size or other mesh characteristics create other complications besides infection, those opinions are not the subject of this challenge.

III. Dr. Ostergard is not qualified to testify about FDA regulatory requirements or what warnings should be included in an IFU.

Ethicon's challenge to Dr. Ostergard's qualifications to testify on FDA regulatory requirements or what warnings should be included in an IFU are based on the Court's recent guidance that a clinical practitioner such as Dr. Ostergard may only testify on these matters if he or she has "additional expertise . . . about what information should or should not be included in an IFU." Defs.' Mem. (Dkt. 2816) at 8 (citing *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (excluding IFU

[2] Of the six Wave 3 cases in which Plaintiffs have designated Dr. Ostergard as a general-causation expert, *see* Ex. A to Defs.' Mot. (Dkt. 2814-1) (listing cases), four involve complaints that do not include allegations that the specific plaintiff experienced a mesh-related infection. Those four cases are *Didomizio v. Ethicon, Inc.*, Civil Action No. 2:12-cv-02436, *Hensley v. Ethicon, Inc.*, Civil Action No. 2:12-cv-03119, *Todd v. Ethicon, Inc.*, Civil Action No. 2:12-cv-02242, and *Warner v. Ethicon, Inc.*, Civil Action No. 2:12-cv-02199.

opinions of Plaintiffs' urology expert Jerry Blaivas, M.D.). Plaintiffs do not address the Court's recent rulings, focusing instead on previous rulings of this Court and others that purportedly support Plaintiffs' assertion that a clinical practitioner may testify on these topics. *See* Pls.' Opp'n (Dkt. 2950) at 9-11. And, while Plaintiffs describe Dr. Ostergard's general qualifications at length, they do not identify any expertise related to FDA regulatory requirements or what information should or should not be included in an IFU that would qualify Dr. Ostergard to testify on these matters, as required by the Court. *See id.* at 1-3, 9-11. Dr. Ostergard's opinions on these issues should therefore be excluded.

IV. Dr. Ostergard's opinions on Ethicon's intentions and narrative review of corporate documents are inadmissible.

Plaintiffs concede that Dr. Ostergard's state-of-mind opinions are inadmissible. *See* Pls.' Opp'n (Dkt. 2950) at 5. They nonetheless contend that Dr. Ostergard "should be allowed to testify about facts from which the jury can infer intent." *Id.* at 12. Plaintiffs do not address the specific opinions challenged by Defendants. *Compare id., with* Defs.' Mem. (Dkt. 2816) at 10. Instead, they assert that Dr. Ostergard "will rely upon Defendants' internal documents to explain what knowledge was available to Defendants and its employees, what information Defendants *should* have known as a manufacturer of mesh devices, and both what the company *should* have done upon learning such information and what the company's own documents factually demonstrate that the company *did* do during the life of Gynemesh." Pls.' Opp'n (Dkt. 2950) at 12. Yet the Court has made clear that it will "exclude state-of-mind and legal-conclusion expert testimony." Defs.' Mem. (Dkt. 2816) at 9 (citing *In re: Ethicon, Inc.*, 2016 WL 4536456, at *4). It will not aid the jury for Dr. Ostergard, a urogynecologist, to provide his opinions of what Ethicon knew based on his interpretation of Ethicon's corporate documents, then offer legal conclusions about what Ethicon should have done with that information. The Court should

exclude the proposed testimony, consistent with its repeated rulings that these are not appropriate subjects of expert testimony. *Id.*

The Court should also exclude Dr. Ostergard's opinions that offer nothing more than a narrative review of Ethicon's corporate documents, as these, too, are unhelpful to the jury. *Id.* Ethicon identified specific statements that constitute narrative reviews of Ethicon's corporate documents. *Id.* at 10 (citing specific paragraphs of Dr. Ostergard's report). Plaintiffs do not address any of this specific testimony. *See* Pls.' Opp'n (Dkt. 2950) at 11. They merely assert, incorrectly, that Ethicon argues that "all narrative testimony is prohibited." *Id.* Plaintiffs do not explain how any of the challenged testimony can survive the Court's repeated rulings that Plaintiffs may not "introduc[e] corporate evidence through expert witnesses." Defs.' Mem. (Dkt. 2816) at 9 (citing *In re: Ethicon, Inc.*, 2016 WL 4536456, at *5). Consistent with these rulings, the Court should exclude the testimony challenged here as inadmissible.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Donald R. Ostergard, M.D. (Dkt. 2814), for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 20, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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